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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,351	10/03/2005	Monique Royer	UF-T398XC1	6228
23557 7590 03/26/2008 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950				
EXAMINER				
ROBINSON, HOPE A				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
03/26/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,351

Applicant(s)

ROYER ET AL.

Examiner

HOPE A. ROBINSON

Art Unit

1652

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-61 is/are pending in the application.
- 4a) Of the above claim(s) 60 and 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51 and 53-59 is/are rejected.
- 7) ☒ Claim(s) 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/888)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. Applicant's election without traverse of Group I (claims 31-34, 37 in part and 38-44) is acknowledged.
2. Claims 1-50 have been canceled. Claims 51-61 have been added. Claims 51-61 are pending. Claims 51-59 are under examination. Claims 60-61 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.
3. The Amendments filed on April 15, 2005 and February 7, 2008 have been received and entered.

Specification

4. The specification is objected to because of the following informalities:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following is suggested:

"Biosynthetic genes and host cells for the synthesis of polyketide antibiotics and method of use".

Figures 3-7 and 10 disclose sequences, however, the Brief Description of the Drawing does not report the corresponding SEQ ID NO:.

Correction is required.

Sequence Compliance

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicant is required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier, i.e., "SEQ ID NO:". The specification discloses sequences that have not been identified by a sequence identifier, see for example, Figures 3-7 and 10. If these sequences have not been disclosed in the computer readable form of the sequence listing and the paper copy thereof, applicant must provide a computer readable form of the "Sequence Listing" including these sequences, a paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable form copies are the same and, where applicable, include no new matter as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). See the attached Notice to Comply with the sequence rules.

Information Disclosure Statement

6. The Information Disclosure Statement filed on April 25, 2007 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Claim Objection

7. Claims 52 and 55 are objected to because of the following informalities:

Claim 52 is objected to as depending from a rejected based claim.

For clarity and precision of claim language it is suggested that claim 55(j) is amended to read, "isolated polynucleotide sequence".

Correction is required.

Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 54-59 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to an isolated transformed host cell and a composition of matter which encompasses nucleotide fragments which are not adequately described. Claim 54 for example recites "...combination of polynucleotide fragments of SEQ ID NOS:1-3", however, there is no indicia as to what the fragments will look like. No correlation is made between structure and function. Thus the claims encompass a genus of nucleotide fragments not adequately described. Therefore, the skilled artisan cannot envision the detailed chemical structure of the enormous amount of peptides encompassed in the claims. Thus, the specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus.

A representative number of species means that the species, which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Further, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention

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is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117).

The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993).

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 53 and 55 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 53 lacks clear antecedent basis for "multiple genetic constructs" since claim 51 only recites "one or more genetic construct".

Claim 55 recites "complementary to the polynucleotide", however, the claim needs to be amended to recite "full complement" to endow function since said complement cannot encode the same protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 51 and 54-59 are rejected under 35 U.S.C. 102 (b) as being anticipated by Huang et al. (Gene, vol. 258, Issue 1-2, pages 193-199, 2000).

Huang et al. teach a structure that is identical to the instant SEQ ID NO:2 (as evidenced by the enclosed alignment). Huang et al. teach a gene (xabA) required for albicidin biosynthesis which encodes a 278 amino acid peptide. Huang et al. teach the use of a host cell such as *E. coli* for said production (see pages 193-196 of the reference). The reference describes the selection of transformants, thus the recited transformed host cell is anticipated (see page 194). Therefore, the limitations of the claims are met by the reference.

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RESULT 2
 AF191324
 LOCUS AF191324 2989 bp DNA linear BCT 12-DEC-2
 DEFINITION *Xanthomonas albilineans* phosphopantetheinyl transferase gene, complete cds.
 ACCESSION AF191324
 VERSION AF191324.1 GI:11065901
 KEYWORDS .
 SOURCE *Xanthomonas albilineans*
 ORGANISM *Xanthomonas albilineans*
 Bacteria; Proteobacteria; Gammaproteobacteria; Xanthomonadales; Xanthomonadaceae; *Xanthomonas*.
 REFERENCE 1 (bases 1 to 2989)
 AUTHORS Huang, G., Zhang, L. and Birch, R. G.
 TITLE Albicidin antibiotic and phytotoxin biosynthesis in *Xanthomonas albilineans* requires a phosphopantetheinyl transferase gene
 JOURNAL Gene 258 (1-2), 193-199 (2000)
 PUBMED 11111057
 REFERENCE 2 (bases 1 to 2989)
 AUTHORS Huang, G., Zhang, L. and Birch, R. G.
 TITLE Direct Submission
 JOURNAL Submitted (01-OCT-1999) Department of Botany, University of Queensland, St. Lucia, Brisbane, Qld 4072, Australia
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 /protein_id="AAG28384.1"
 /db_xref="GI:11065901"

Art Unit: 1652

RESULT 2
 AF191324
 LOCUS AF191324 2989 bp DNA linear BCT 12-DEC-2
 DEFINITION *Xanthomonas albilineans* phosphopantetheinyl transferase gene, complete cds.
 ACCESSION AF191324
 VERSION AF191324.1 GI:11065901
 KEYWORDS .
 SOURCE *Xanthomonas albilineans*
 ORGANISM *Xanthomonas albilineans*
 Bacteria; Proteobacteria; Gammaproteobacteria; Xanthomonadales; Xanthomonadaceae; *Xanthomonas*.
 REFERENCE 1 (bases 1 to 2989)
 AUTHORS Huang, G., Zhang, L. and Birch, R. G.
 TITLE Albicidin antibiotic and phytotoxin biosynthesis in *Xanthomonas albilineans* requires a phosphopantetheinyl transferase gene
 JOURNAL Gene 258 (1-2), 193-199 (2000)
 PUBMED 11111057
 REFERENCE 2 (bases 1 to 2989)
 AUTHORS Huang, G., Zhang, L. and Birch, R. G.
 TITLE Direct Submission
 JOURNAL Submitted (01-OCT-1999) Department of Botany, University of Queensland, St. Lucia, Brisbane, Qld 4072, Australia
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 /mol_type="genomic DNA"
 /strain="LS155"
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 CDS 1283..2119
 /function="involved in albicidin and phytotoxin biosynthesis"
 /note="XabA; similar to EntD and to PPTases involved in antibiotic and fatty acid biosynthesis in bacteria; contains two conserved motifs of PPTases"
 /codon_start=1
 /transl_table=11
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 /protein_id="AAG28384.1"
 /db_xref="GI:11065901"

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Best Local Similarity		100.0%;	Pred. No. 0;		
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				Indels	0;
					Gaps
					0;
Qy	1	GAATTACGCGATGTGGCTGCGGTGCGCGGCACCGCCTTGCCCTGCGGCACCAAGTAGTT	60		
Db	1	GAATTACGCGATGTGGCTGCGGTGCGCGGCACCGCCTTGCCCTGCGGCACCAAGTAGTT	60		
Qy	61	GCGGCCGTAACCCGGCTTGACGTGACCTTTGTGCCGAGGCCGCCAGGTTGGTGACTTT	120		
Db	61	GCGGCCGTAACCCGGCTTGACGTGACCTTTGTGCCGAGGCCGCCAGGTTGGTGACTTT	120		
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Db	121	CTGCAGAAAGATCAATTGCATGGCGTTACTCCGTTATTGTTAGCGCGCGCATGCGGCCA	180		
Qy	181	CCGCAACGCGTGCTGTCCGAATAGGACGGGATTGGATTGCGCGGAGTGGCAGATGTACCC	240		
Db	181	CCGCAACGCGTGCTGTCCGAATAGGACGGGATTGGATTGCGCGGAGTGGCAGATGTACCC	240		
Qy	241	AACCGACACCCGGCGGTTGCTTCGGTGCCTGCACACGGGAATGCGCGCGCTTCCGAACGA	300		
Db	241	AACCGACACCCGGCGGTTGCTTCGGTGCCTGCACACGGGAATGCGCGCGCTTCCGAACGA	300		
Qy	301	CTCGGATCAAACGTCGTGGTTGTCCGTGTACGGGATCAGCGCCAGGAAACGCGCACGCTT	360		
Db	301	CTCGGATCAAACGTCGTGGTTGTCCGTGTACGGGATCAGCGCCAGGAAACGCGCACGCTT	360		
Qy	361	GACCGCCGTGCGCAACTGACGCTGGTACTTTGGACTTGGTGCCGGTACACGCGCTCGGCAC	420		
Db	361	GACCGCCGTGCGCAACTGACGCTGGTACTTTGGACTTGGTGCCGGTACACGCGCTCGGCAC	420		
Qy	421	GATCTTGCCGTTCTCGGTGAGGTACTGGCGCAGGGTGTTGAGATCCTTGTAGTCGATCTC	480		
Db	421	GATCTTGCCGTTCTCGGTGAGGTACTGGCGCAGGGTGTTGAGATCCTTGTAGTCGATCTC	480		
Qy	481	TTTGACGCCCTCGCGGTTGAATTTGCAGAACTTGCACGACGGAAGAACTTGGACATGGA	540		
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y 541 CCTGCTCCTTAGCGGCTTCGACGGCTCGCCGTCGGCTTCGTTGGCGGCGGGGACACA 600
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b 541 CTGCTCCTTAGCGGCTTCGACGGCTCGCCGTCGGCTTCGTTGGCGGCGGGGACACA 600
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b 601 TCGCCATCGTCGTCGTCGCGACGACGCTCACCACGGTCGGGCTTGTCGCCCTTCTCG 660
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b 661 TCCTTGCTCTTCATGATCAGCGACTGCTCGGTGTCGGCGCCATCGCGCTTGATCGCCAGG 720
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b 721 TGACGCAGCACGGCGTCTTTGAAGCGGAAGCTCTCGACCAACTGCTCAGCACGGCTGA 780
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b 781 TCCACTTCGATGTTGAGCATGACGTAGTGCCTTCACCAGATTCTGGATCGGGTAGGCC 840
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b 841 AACTGTCGGCGGCCCAAGTCTTCCAGCGGTGGATGCTGCGCCGCCGCTTCTCGACCAGC 900
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b 1021 AGCCCCCGCAGGTGGCGGTGGAGCAAGGGTTCCCGCCGAATAGGCGCAGGAAGCCAAT 1080
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b 1081 AAGTATGGCAGCGCCCTTGACCAATGACAAGCTCATGCACCCAGGACGCCCGCTCTGCTC 1140
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Qy 1861 CGCGCAGTGGCCGAAGACCTGCTGCTGACCGCACTATTTTCGGCCAAAGGAAAGCTGTT 1920

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Qy 1921 CAAAGCCGCCCTACAGCGCGGTGGGACGCTACTTCGACTTCAGCGCGGCACGCTGTGCGG 1980
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Qy 2461 ACGCGTGCAAAACGCGCGGGGTGAGCGGGATGGCCATGACGAACGACTCCAACGACTTG 2520
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Qy 2521 CGATACGACATTATACGACCGATGCCCGCAACGCCCTCGCAAGCGCTACGCTCCAGCCAGT 2580
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Db 2521 CGATACGACATTATACGACCGATGCCCGCAACGCCCTCGCAAGCGCTACGCTCCAGCCAGT 2580
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Ov 2581 ACACCTTGTTCATTCCATATCGAGCCACTGCGGCGAGGATTCAAGTCATGACGGTGGTGA 2640

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Qy      2701  GGTCCGTACCCGGCGGACTCCAAAGCGGGGCTGTCTTCGTCAATGTCAGCGACGGTTC 2760
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Db      2701  GGTCCGTACCCGGCGGACTCCAAAGCGGGGCTGTCTTCGTCAATGTCAGCGACGGTTC 2760

Qy      2761  CTGCTTCGCGCCGATCCAGGTGGTGGCTCCGGCCGCGCTGCCAACTACGAACCGGAAGT 2820
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Qy      2821  GAAGCGCCTGACCGCGGGCTGCGCGGTGATCGCGCGCGGGCACCTGGTCGCTCGCAAG 2880
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11. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652